# EPA Registration Jacket 70051-46 Vol. 1

S; 761958			Print Letter
Regulatory Type: Product Registration - Sec	tion 3 Resubmission C	Yes <b>F</b> No	Enter More Information
Application Type: Miscellaneous Receipt	Fee For Service: C	Yes © No	
Company: 70051 CERTIS USA, LLC	<u>V</u>		
Risk Manager: Biologicals & Pollution Prev	ention Division, PM Team 92	<u> </u>	
Product #: 70051-46 Product N	larne: SPOD-X LC	$ \wedge$ $\wedge$	NIKS
Override <b></b> #		IV I	NIZI
THE RESERVE TO SERVE THE PROPERTY OF THE PROPE	e Too ct Name:		
Application Date: 02-Jun-2004	OPP Rec'vd Date: 02-Jun-2004	iė R	eceipt Content
Front End Date: 02-Jun-2004	Risk Manager Send Date: 10-Jun-2004	<u>iė</u> j	
Fast Track:	Ingredient 🗂		
Receipt Description:			
final printed labels.	<u> </u>	New Ingredient Request Date	
		New Ingredient	
		Received Date	
Form A Signature Date	Formitia 🖵	Signature Date	

RC 37 DA 4/30/07.

# NON FEE ITEM

**DIVISION:** Biopesticides and Pollution Prevention

BRANCH: MPB

EPA FILE SYMBOL/REG. NO: 70051 - 46

PIN PUNCH/START DATE: 6-3-04

6-9-04 **BPPD DATE:** 

PR 86-5 PASS DATE: N/A

ACTION CODE: 331

RAL: Har Nancy Tyler
REMARKS: FINAL Printed Culds

Decision Seq.	339518	Action Code: 450,Gol	d Seal Letter;,0			Decision Status
FFS Start Date:			FFS Origi	nal Decision:	<u></u>	Tracking
Due Date:			FFS E	UP Decision:	<u></u>	Create Resubmission
P Target Due Dt:	1	<u></u>	FFS Sec	ct3 Decision:	<u></u>	FFS Delay Letters
Registran sponse Due Date		— [iè]	Start/Stop Clock	FQPA Clock:		FFS Letters
Current Status  Meetings & Mi  Decision Own	lestones	29-Mar-2004)  UFFS Information  Receipts	Data Package	) mi Dou	uced Risk	
Receipts		Staff Member	Reg/DCI Number	Admin Due Dt	uccu ( (lor	Response
了S: 754796	Tyler, Nano	<b>-v</b>	70051-46	13-Feb-2004	" half   half   77   he haw	SPONSE TO APPLICATION

MAR 29 2004 RC 38

# FM 90: Janet Andersen

REGISTRANT/COMPANY NAME:			ack: Yes No
Cenfis	, t		ver <u>Ylev</u> ed by <u>PH</u>
EPA REG./FILE SYMBOL 70051- Spod ACTION CODE 350	46 -X20	need to	lf Fast Track, you may change Reviewer's in PRAT.]
(New A.I/EUP'S/Tolerances: Yes□ N	(o□)	5 old	Seul
DATE OF APPLICATION 8-7-0	<u> </u>		
EPA RECEIVED DATE 8-9-02	<i>?</i>		w.
BPPD RECEIVED DATE 9-22-0	2		
SUBMISSION BARCODE <u>S 628</u>	738	·	
ASSIGNED IN PRAT: Yes□ No□			
COMPLETED BY hogh DATE	/		
LOGGED IN BRATS: Yes No DA	TE <u>9///</u> COMP	LETED B	y <u>M</u>
RAL RECEIVED DA	ATE		
عي ع	عرفي على على على على على على ع	ر هر هر هر.	عرعر عرعرعرعرعرعرعرعرعرعر
FINAL ACTION			
RESPONSE CODE: 38			
RESPONSE DATE: 9/10/02			
MOS:(1) Cite All(4) Not Applicable(8) Selective	CRP Restricted Use: Manufacturing Use: Exclusive Use:	Yes□ Yes□ Yes□ Yes□	No

# FBPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:  Certis USA-LLC.	Fast Track: Yes No No Reviewer Assigned by Poly
EPA REG./FILE SYMBOL 70051-44  ACTION CODE 350	[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]
(New A.I/EUP'S/Tolerances: Yes No No No DATE OF APPLICATION 1-14-07	Gold Seal
EPA RECEIVED DATE /-/4-02	· · · · · · · · · · · · · · · · · · ·
PM RECEIVED DATE $/-/4-02$ SUBMISSION BARCODE $56088/3$	
ASSIGNED IN PRAT: Yes No DATE 1-16-0  LOGGED IN BRATS: Yes No DATE 1-2	
HALACTION	* * * * * * * * * * * * * * * * * * * *
RESPONSE CODE: 38	
RESPONSE DATE: 1-23-01	
MOS:(1) Cite All(4) Not Applicable(8) Selective	
CRP Yes No	

# REGISTRATION CHRONOLOGY

Action Code	Record No./ Ref. No.	Response Code	
350	70051-46	Event Gold Seal	38
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June 2, 2004

Certis USA 9145 Guilford Road Suite 175 Columbia, MD 21046

(301) 604-7340

FAX (301) 604-7015 www.certisusa.com

Mr. Dennis Szuhay
Branch Chief, Microbial Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
US Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Re: Final printed labeling for Certis USA, L.L.C., EPA Co. No. 70051

Dear Mr. Szuhay:

Certis USA, L.L.C. is respectfully submitting the enclosed final printed labeling that incorporates minor changes (Notifications) into the labeling for the following products:

- 1) Spod-X LC, EPA Reg. No. 70051-46
- 2) Agree, EPA Reg. No. 70051-47
- 3) CLV LC, EPA Reg. No. 70051-41
- 4) Thuricide HPWP, EPA Reg. No. 70051-53
- 5) San 420 I Technical Concentrate, EPA Reg. No. 70051-70
- 6) Lepinox XL WDG, EPA Reg. No. 70051-92
- 7) Lepinox XL OF, EPA Reg. No. 70051-94
- 8) Javelin WG 2, EPA Reg. No. 70051-98
- 9) Agree 50 WP, EPA Reg. No. 70051-99

Enclosed in support of this action are: form 8570-1 and 3 copies of each final printed label with changes incorporated. No other changes have been made to these labels. Thank you for your assistance in this matter. Please do not hesitate to contact me if you have any questions about this submission. I can be reached by telephone at 301-483-3806 or by email at cdively@certisusa.com.

Sincerely,

Christine A. Dively -

Director of Regulatory Affairs

Enclosures

Please read instructions on reverse before completing form.	Form Ap	proved. OMB No. 2070	0-0060, Approvel expires 2-28-95				
SEPA Environmental Protec		Registration					
Washington, DC 2		✓ Amendmen	)t				
Applica	tion for Pesticide - Sec	tion I					
1 . Company/Product Number	2. EPA Product Mar	nager	3. Proposed Classification				
70051-46	Dennis Szuhay		None Restricted				
4. Company/Product (Name) Spod-X LC		Microbial Pesticides Branch					
5. Name and Address of Applicant (Include ZIP Code)	, · · · · · · · · · · · · · · · · · · ·		with FIFRA Section 3(c)(3)				
Certis USA, L.L.C.	(b)(i), my product to:	is similar or identical i	in composition and labeling				
9145 Guilford Road, Suite 175 Columbia, MD 21046	1 ***						
Check if this is a new address	Product Name						
		NOTIE					
Adrama Euplaio baloui	Final arinta	NOTIFIC d labels independent to the dated Application of By:	AT/ON				
Amendment - Explain below.	Agency let	d labels in the tights to	h-3				
Resubmission in response to Agency letter dated	"Me loo"	Application of By.	20-04				
Notification - Explain below.	Other - Exp	olain below.	Alex				
Explanation: Use additional page(s) if necessary. (For sec	tion I and Section II.)						
Notification to revise the phrase "Spod-X LC is an IVP (Insecticidal Virus I over the warranty statement. Revised "Oz. per acre" in the application rat submission. This notification is consistent with the provisions of PR Notic the confidential statement of formula of this product. I understand that it is this notification is not consistent with the terms of PR Notice 98-10 and 40 penalties under sections 12 and 14 of FIFRA.	tes table to read "FI. Oz. per acre". Three e 98-10 and EPA regulations at 40 CFR a violation of 18 U.S.C. Sec. 1001 to will	e copies of final printed labelin 152.46, and no other changes Ifully make any false statemer	ng are also included in this s have been made to the labeling or nt to EPA, I further understand that if				
	Section - III						
1 . Material This Product Will Be Packaged In:							
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging	2. Type of Contr	ainer				
Yes	Yes	V Pla	ital stic				
If "Yes" No. per	T NO	No Glass  (as" No per Paper					
** Certification must Unit Packaging wgt. Submitted If "Yes" No. per Unit Packaging wgt.	If "Yes" No. per Package wgt containe		ner (Specify)				
3. Location of Net Contents Information 4. Size(s) F	Retail Container	5. Location of Label Dir	rections				
Label Container	1 quart	on container					
6. Manner in Which Label is Affixed to Product Lith Pap	ograph Othe er glued nciled	r					
	Section - IV						
1. Contact Point (Complete items directly below for identifica	tion of individual to be contacted,	if necessary, to process	this application.)				
Name Christine A. Dively	Title Director of Regulatory Affairs	1 .	phone No. (Include Area Code) -483-3806				
Certifi	cation		6. Date Application				
I certify that the statements I have made on this form a I acknowledge that any knowlingly false or misleading s both under applicable law.			Received (Stamped)				
2. Signature	3. Title		•••••				
Christine A. Deiely-	Director of Regulatory Affairs	***	•				
4 . Typed Name	5. Date		••••				
Christine A. Dively	may 28, 2004	1ay 28, 2004					

# Spod-X.

# INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

# FOR ORGANIC PRODUCTION

OMRI Listod Organic Materials Review institute

Active Ingredient:\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua Date Reviewed 59.36%

Other Ingredients: 99.36%

Total: Reviewed 1899%

This lot contains at least 2 billion OBs/ml.

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS 1 QUART EPA Reg. No. 70051-46 EPA Est. No. 70051-CA-001

Manufactured by Certis USA, L.L.C. 9145 Guilford Road Suite 175 Columbia, MD 21046

#### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

SPOD-X LC is an Insecticidal Virus for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

# PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS):

**CAUTION:** Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

## FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If inhaled: Move person to fresh air, If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

#### PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- · Long-sleeved shirt and long pants
- · Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **Engineering Control Statements:**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

#### **USER SAFETY RECOMMENDATION**

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

**ENVIRONMENTAL HAZARDS:** For Terrestrial Uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

# DIRECTIONS FOR USE ....

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product irra way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State of Tribe, consult the agency responsible for pesticide regulation.

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#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- · Coveralls
- · Waterproof gloves
- · Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates. Thorough spray coverage is essential for good insect control. Apply SPOD-X LC by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Use the application amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application. Use of a spreader/sticker and ultraviolet screening agent can enhance the performance of this product. Fill the mix tank with desired quantity of water. Use agitation during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Mix final formulation for 10-30 minutes.

#### **APPLICATION RATES**

CROP	RATE				
	Billions Obs Per Acre	Mis Per Acre	Fl. Oz Per Acre		
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4		
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4		

CROP		RATE	
	Billions Obs Per Acre	Mis Per Acre	FI. Oz Per Acre
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NONCHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC can be applied up to and including the day of harvest and storage. Shake well before using.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

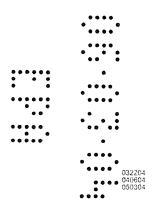
**STORAGE:** Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.



# Spod-X.

# **INSECTICIDAL VIRUS**

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

# FOR ORGANIC PRODUCTION

# KEEP OUT OF REACH OF CHILDREN CAUTION



NET CONTENTS 1 QUART EPA Reg. No. 70051-46 EPA Est. No. 70051-CA-001

Manufactured by Certis USA, L.L.C. 9145 Guilford Road Suite 175 Columbia, MD 21046



### SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

SPOD-X LC is an Insecticidal Virus for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

## PRECAUTIONARY STATEMENTS:

### HAZARDS TO HUMANS (AND DOMESTIC ANIMALS):

**CAUTION:** Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with skin, eyes or clothing. Harmful if inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

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If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

## PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- · Long-sleeved shirt and long pants
- · Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **Engineering Control Statements:**

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment break-down.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

**ENVIRONMENTAL HAZARDS:** For Terrestrial Uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

# DIRECTIONS FOR USE ....

It is a violation of Federal law to use this product in a france inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for perticide regulation.

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#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

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- Coveralls
- Waterproof gloves
- · Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

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#### **APPLICATION RATES**

CROP	RATE						
	Billions Obs Per Acre	Mis Per Acre	Fl. Oz Per Acre				
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4				
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4				

CROP	RATE					
	Billions Obs Per Acre	MIs Per Acre	Fl. Oz Per Acre			
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4			

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NONCHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC can be applied up to and including the day of harvest and storage. Shake well before using.

### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

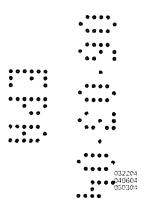
STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

#### WARRANTY

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Christine A. Dively Certis USA 9145 Guilford Road, Suite 175 Columbia, MD 21046

DEC 22 2003

Dear Ms. Dively:

Subject: Labeling Amendment

Spod-X LC

EPA Reg. No. 70051-46

Your submission dated 10 September, 2003

The labeling amendment referred to above submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been received and reviewed and the labeling is acceptable. Please note that your organic language to the label is acceptable. Please submit three (3) copies of your final printed labeling incorporating the changes prior to releasing your product for shipment. A stamped copy is enclosed for your records.

Should you have any questions regarding this correspondence, you may contact Leonard Cole directly at 703.305.5412. We hope that you find this information helpful.

Sincerely,

Dennis Szuhay, Branch Chief

Microbial Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511C)

Enclosure

CONCURRENCES							
SYMBOL ) 75/10	7511 C						
SURNAME COLF	Szuhay						
DATE 12/02/03	12-22-03						
OFFICIAL SIVE COPY							

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL RIZE COPY

# Spod-X°LC

# INSECTICIDAL VIRUS

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

# FOR ORGANIC PRODUCTION

Active Ingredient:\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of *Spodoptera exigua* 

**Inert Ingredients:** 

Total:

\*This lot contains at least 2 billion OBs/ml.

0.64%

99.36%

100.00%

# CAUTION KEEP OUT OF REACH OF CHILDREN

## **NET CONTENTS 1 QUART**

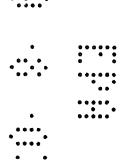
EPA Reg. No. 70051-46 EPA Est. No. 70051-CA-001

Manufactured by Certis USA 9145 Guilford Road Suite 175 Columbia, MD 21046



DEC 2 2 2003

Under the Federul Insecticides, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 70051-44



### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of equipment washwaters. **STORAGE AND DISPOSAL:** Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

**PESTICIDE DISPOSAL**: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on

site or in an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

#### PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

#### FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

**If inhaled:** Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

### PERSONAL PROTECTIVE EQUIPMENT:

Applicators and other handlers must wear:

- · Long-sleeved shirt and long pants
- · Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard. Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours. PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- · Coveralls
- Waterproof gloves
- · Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. Apply SPOD-X LC by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Use the

application amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

Use of a spreader/sticker and ultraviolet screening agent can enhance the performance of this product. Fill the mix tank with desired quantity of water. Use agitation during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Mix final formulation for 10-30 minutes.

### APPLICATION RATES

CROP	RATE		
	Billions Obs Per Acre	Mls Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 – 200	50 – 100	1.7 – 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 – 200	50 – 100	1.7 – 3.4
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 – 200	50 – 100	1.7 – 3.4

MAKE APPLICATION WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC can be applied up to and including the day of harvest and storage. Shake well before using.

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

SHAKE WELL BEFORE USING

M081103 M081803 OMRI

# SPOD-X°LC

# A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully.

Active Ingredient:\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64% 99.36% 100.00%

Inert Ingredients: Total:

\*This lot contains at least 2 billion OBs/ml.

This lot contains at least 2 billion obs/fill.

## USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

**ENVIRONMENTAL HAZARDS:** Do not contaminate water when disposing of equipment washwaters.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or in an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

### PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

### **FIRST AID**

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.

Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Hot Line Number: 1-800-255-3924.

# CAUTION KEEP OUT OF REACH OF CHILDREN

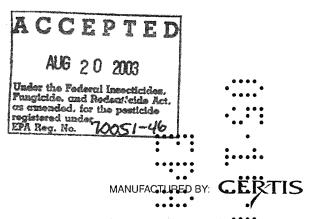
#### **NET CONTENTS 1 QUART**

EPA Reg. No. 70051-46 EPA Est. No. 70051-CA-001

**PERSONAL PROTECTIVE EQUIPMENT:** Applicators and other handlers must wear:

- · Long-sleeved shirt and long pants
- · Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.



Certis USA, L.L.C. • 9145 Guilford Road, Suite 175, Calumbia, MD 21046

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exemptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

Coveralls • Waterproof gloves • Shoes plus socks.

## GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If spreader/sticker or ultraviolet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

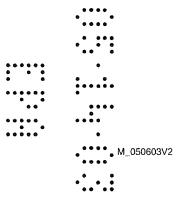
RECOMMENDED /	APPLICATION	RATES	
CROP CROP		RATE	
	Billions OBs Per Acre	Mis Per Acre	Oz Per Acre
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	100 - 200	50 - 100	1.7 - 3.4
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	100 - 200	50 - 100	1.7 - 3.4
FLORICULTURE: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	100 - 200	50 - 100	1.7 - 3.4

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage. Shake well before using.

Certis USA, L.L.C. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

# SHAKE WELL BEFORE USING



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I, Dennis Szuhay, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

Certis USA 9145 Guilford Road, Suite 175 Columbia, MD 21046

**EPA REGISTRATION NUMBER** 

70051-46

NAME OF PRODUCT

Spod-X LC

Dennis Szuhay, Chief
Microbial Pesticides Branch

3-16-04

[Date]

CONCURRENCES							
SYMBOL ) 75// C	75/1C						
SURNAME) Tyles							
DATE 3-15-04	3-16-09						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY



Certis USA 9145 Guilford Road Suite 175 Columbia MD 21046

(301) 604-7340

FAX (301) 604-7015 wr:rm.certisusa.com

February 11, 2004

Ms. Nancy Tyler Biopesticides and Pollution Prevention Division (7511C) Office of Pesticide Programs U.S. Environmental Protection Agency 1921 Jefferson Davis Highway, Crystal Mall 2 Arlington, VA 22202

RE: Gold Seal Requests

Dear Ms. Tyler:

Certis USA L.L.C. (EPA Company No. 70051) respectfully requests that EPA provide three Gold Seal Letters for each of the following products:

 Product
 EPA Registration No.

 Agree 50 WP
 70051-99

 Cyd-X
 70051-44

 Javelin WG2
 70051-98

 Spod-X LC
 70051-46

Gemstar LC 70051-45
Agree WG 70051-47

We have included three copies of each label to assist in this request. Once the Gold Seal Letters are complete, please forward them to my attention at the following address:

Certis USA L.L.C. 9145 Guilford Rd. Suite 175 Columbia, MD 21046

Please feel free to contact me if you have any questions about this submission. I can be reached by telephone at (301)483-3806 or by email at cdively@certisusa.com.

Sincerely.

Christine A. Duely\_

Director of Regulatory Affairs

Enclosures

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

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Certis USA L.L.C. 9145 Gilford Rd, Suite 175 Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

NAME OF PRODUCT

Spod-X LC

Phillip Hutton, Chief
Microbial Pesticides Branch

SEP 1 6 2002

[Date]

	CONCURRENCES							
SYMBOL	7511							
SURNAME	Tyler			•••••	***************************************	**********		
DATE	9-12-12			*************	•••••••	••••••		

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL 212E COPY



Certis USA 9145 Guilford Road Suite 175 -Columbia, MD 21046 (301) 604-7340 FAX (301) 604-7015 www.certisusa.com

August 07, 2002 ^

Nancy Tyler
U.S. Environmental Protection Agency
Office of Pesticide Programs (BPPD)
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Certis USA Gold Seal Request

Dear Ms. Tyler:

Certis USA L.L.C. (EPA Company No. 70051) respectfully requests EPA to provide three Gold Seal Letters for each of the following 9 products:

9 Products	EPA Registration No.		
Neemix	70051-5		
Neemix 4.5	70051-9		
Spod-X LC <sup>∨</sup>	70051-46		
Gemstar LC	70051-45		
Agree WG	√70051 <b>-</b> 47		
Teknar HP-D	<i>≨</i> 70051-51		
Thuricide 48LV ·	<b>/</b> 70051-57		
Javelin WG	.70051-66		
Thuricide Technical Concentrate	70051-68		

Please find enclosed copies of the most recent EPA approved labels (3 copies for each product). Once the Gold Seal Letters are complete, please forward them to my attention at the following address:

Certis USA L.L.C. 9145 Guilford Rd. Suite 175 Columbia, MD 21046

# SPOD-X® LG

### A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

SPOD-X LC is an IVP (Insectiodal Virus Product) for control of the caterollius of the baet armyworm on field and greenhouse gross and omamentals. Read this label carefully.

> Adive Inoxedient':

Polyhedral occusion bodies (08s) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64%

Inert Ingredients:

99.16%

"This lot contains at least 2 billion OBs/mi

ESTABLISHMENT No. 67250 N.-1 EPA REGISTRATION No. 58788-7

# CAUTION KEEP OUT OF THE REACH OF CHILDREN

#### PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS); Avoid inhalation or contact with skin, eyes or civiling. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-skeyed shirt and long pants . Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergern and hot water. Keep and wash PPE separately from other foundry.

STATEMENT OF PRACTICAL TREATMENT: In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration it indicated. Get medical attention it initation persists.

## USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using lobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters. STORAGE AND DISPOSAL: Do not contuminate water, food, or feed by storage or disposal. Open dumping is prohibit-

STORAGE: Store this product in original sealed container in a cool, dry place inaccessable to children and pets. Store at temperatures below 90°F. Biografify may be impaired by storage above 90°F. Storing the product in a freezer or reingerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or misale that cannot be used should be disposed of on site or at an approved warie disposal lacitity in accordance with Federal and local regulations.

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DIRECTIONS FOR USE

This a violation of Federal law to use this product in a motional instruction with its likeling. Do not upply this product in a way that will control workers or other persons, either deepty or through date. Only protected handers may be in the area during application. For any requirements 1 1 chic to your State or Tribe, consult the agency responsible for presides regulation.

#### AURICULTURAL USE REQUIREMENTS

8661 Use this product only in ecconducts with its libbing and with the Highest Production Standard 40 CFR pain 170. This Standard contains use presposation in account and a month of an earlier manner receives an operation of account and earlier an 17: In this bost only apply to use of this product that are constructly the norther protection Standard.

Count with or above norther entry this beated are as during the restricted entry trianval (NED) of 4 hours.

PPE required by surly entry to beened was shall is permitted under the Horizon Protection Standard and that functives contract with any thing that has been treated, such as plants, soil, or water, is:

Coveralls - Waterproof gloves - Street plus social

#### **GENERAL INFORMATION**

SPOD-X LC is a highly salerting isoporticate for use aquires the trasects and on the crops lated on this label. Aboves lotter these directions: Treat abantures are young (early instant) and are actively leading. Apply before activities damage has occurred tithen insect infertacing are he.

Through spray towards is essected by good fraed control. SPODIX LC should be applied by committee on a small application a equin of which quarties of water to provide thorough coverage of interest plants without a not. The small of least needed persons and depend on weather, spreading and local experience. Generally, use the recommended amount of SFODIX LC in 30-100 gustars of water persons for ground applications. in at least 5 gattors of water for sacral application.

A Social field that and whiteled creating a partition of the performance of this product.

Fill the mod fund with desired quarter of water, Agitation should be used during intering. It is spreader/inflorer or other-index screen is used, add provide the addition of SPCO-X LC. Within the can be reduced by premixing SPCO-X LC with a while amount of water and vigorously experting before a story. the lank. Fruil formulation should be missed for 10-30 minutes.

#### RECOMMENDED APPLICATION RATES

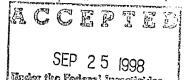
CRÓP		TE		
	Alkons Ods Set Acce	Nets Per Asca	Ca Pay Mill	
Yeg riables: Tamulors, letitus, calòsge, beans, peppers, celery, escavole, sweet com, pras, sepuragus, beels, ceuditiwer, quouwber, braccol, onon	100 - 200	50 - 100	1.7 - 3.4	
Other Crops; Conon, etate, soptama, pearles, potatos e coro, where enfectuous, leducod, rentimes, expedients	100 - 200	50 - 100	1.7 - 3.4	
Florkviture: Chrysanthan in, gipsophila, gartara, ecca, camellan, ézakéa, gledioka, cyclaman, Liaritaelle, gararéin, Belmenta	100 - 200	50 - 100	1.7 • 3.4	

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAIL LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

This product is for use on both field and green house grops and order higher USE MCH. CHEOFORKATED WATER AT A PHINE AT TO ENTIRE SPRAY TAX LIX. SPOD-X LC may be applied up to and inducing the day of harvest and storage. Shalle well believe using.

Orth Genetics International makes no warranty express or tripled, including the warrantes of menthaloidably under fivess for any parcoular purpos concerning his authors except those which are morained on the label

Orco Genetics International - A Subsidally of bicers + 10150 Old Columbia Road + Columbia, MD 21046



Under the Federal inscribition. Premistale and Rederitate in. en unrendeel. for the presiden

# United States Environmental Protection Agency

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA; A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product. Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration and/or the product label for the product listed below. EPA has issued a registration number for the product listed below to:

Certis USA L.L.C. 9145 Guilford Road, Suite 175 Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

**NAME OF PRODUCT** 

Spod-X LC

Phillip Hutton, Chief Microbial Pesticides Branch

JAN 23 2002

[Date]

		 CON	CURRENCES			
SYMBOL >	7511C					
SURNAME	Dyler					
DATE F EPA Form 1320-	1-16-02				CIAL FILE COPY	25

# OF ACENCY OF THE PROPERTY OF T

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

I, Phillip Hutton, Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency ("EPA"), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the products may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

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Certis USA L.L.C. 9145 Guilford Road, Suite 175 Columbia, MD 21046

EPA REGISTRATION NUMBER

70051-46

NAME OF PRODUCT

Spod-X LC

ALON LESS

Phillip Hutton, Chief Microbial Pesticides Branch

JAN 23 2002

[Date]

# SPOD-X® LC

A Liquid Concentrate Biological Insecticide For Control of Beet Armyworm

SPOO-X LC is an RYP (Insecticidal Virus Product) for control of the caterpillars of the beet army room on held and greanbouse crops and ornamentals. Read this label carefully.

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Polyhedral occassion bodies (OBs) of the

nudear polyhedrosis vins di Spodoptere exigua

0.64% 99.18%

inen ingreoferns:

This kil contains at least 2 billion OBs/rill

ESTABLISHMENT No. 87250-IL-1 **EPA REGISTRATION No. 58788-7** 

# KEEP OUT OF THE REACH OF CHILDREN CAUTION

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS (AND DOMESTIC ANIMALS): Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray prist.

PERSONAL PROTECTIVE EQUIPMENT: Applicables and other handlers must wear:

Long-sleened shirt and long pants . Shoes plus socks.

Follow manufacturer's instructions for clearing and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other banday.

STATEMENT OF PRACTICAL TREATMENT: In case of contact with eyes fush with plenty of water for at least 15 minules. If on skin, wash thoroughly with soap and water, If inhaled, remone victim to fresh air. Apply respiration if indicated. Get modical exection il initation persists.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using lobacco, or using the tollet.

ENVIRONMENTAL MAZARIOS: Do not contaminate water when decesing of equipment washwaters. STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibit-

ed. Do not re-use empty containers. STORAGE: Store this product to original scaled container in a cool, dry place inaccessible to children and pets. Store at

temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Seering the product in a live zer or refrigerator will extern its shell-life.

alor are entered as severane. PESTICEDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pestiode, spray minture or insate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulation. CONTAMER DISPOSAL: Plastic container - implementary (or equipment). Then offer for recycling or reconditioning or purchare and dispose of in a sanking landiff, or by incineration, or it allowed by State and local authorities, by humany. If humans and dispose of in a sanking landiff, or by incineration, or it allowed by State and local authorities, by humany. If humans are disposed of the sanking landiff, or by incineration, or it allowed by State and local authorities, by humany. If humans are landiffications are supported by State and local authorities, by humany. If humans are landiffications are supported by State and local authorities, by humany. If humans are landiffications are supported by State and local authorities, by humany. If humans are landiffications are supported by State and local authorities, by humany. If humans are landiffications are supported by State and local authorities, by humany.

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DIRECTIONS FOR USE

à is a violation of Federal lieu to use this product in it marrier both safeth with its librieling. Do not upply the product in a resp that will consuct works to other persons, either descript of frough of its Chily process fareflines may be in the seas during application. For any requirements upparation you follow of Tribe, consult the approxy responsible for players that are if the consult the approxy responsible for players that the first of the first o

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its listeling and with the Winter Protection Standard, 40 CFR pure 17th. This Standard contains requirements for the protection of agricultural workers on forces, breast, pursues and great-bases, and has derived a gradually extracted, in contains requirements for from the contains and common protection of the standard register forces of the proteining to the statisticate of the standard proteining forces and exception proteining to the statisticate of the proteining for the standard register of the standard proteining forces and the standard register of the standard registe

Consolir - Waterproof gloves - Stoon plus socia

GEMERAL PEFORMATION

SPOCIALC is a highly selective baseciated for use against the resolated on the stated on this label. Merays follow these directions:

Treat when larvae and young fearly instant and are actively leading. Apply before extensive damage has cocurred. When treat intertactors are heavy, use the higher later rates.

user to request users. The provided in the special for special control, SPOON, LC should be applied by conventional ground or serial application excipance with questions of weath provided for user will depend on measure, typey converted to prevent forcing to control of the serial control of the serial provided for one will depend on measure, typey control and local expectations. Generally, user the securate and amount of SPOON, LC in 20-100 palons of valuer for sorial explication and final least of pulsation of sector for sorial explication and final least of pulsation of sector for sorial explication.

A Spreakelelatur and all articles to exemp agent may extense the performance of this product.

A Spreakelelatur and all articles to exemp agent may extense the performance of this product.

For action of SPODX LC, bloomy three case to extend by permitting \$100 \times \times \text{in a tense and vigorously actions to tense acting to the tark. Final formulation should be exceed by 10-30 windows.

#### RECOMMENDED APPLICATION RATES

CROP	RA	TE	
	Billions Offis Opt Acre	Per Ascr	72 875/119
Vegetables: Tenadise, tenade, colitope, bases, peggers, colory, ascarde, sevest com pess, asparagus, beets, cauliforest, ascarder, braccal, orien	100 - 200	50 - 100	1:7-3.4
Other Crops: Crisos alkál, szybasza, paarist, politica, cort, whall sweetpolitics, lobaczy, szefizme, szysztec it	100 - 200	50 - 100	-1.7-3.4
Ploriculture: Construction, geographia, perfora rose, corrector, acolea gladidus, episaran, karipasia, geograph, Boxestia	100 - 200	50 - 100	1.7 - 3.4

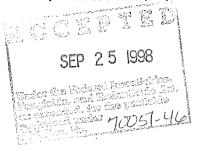
APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR, LARVAE MUST MIGEST OSS TO BE DIFFECTED. WHICH IS THE CASE WHEN THEY CONSTRUE SPRAYED PLANT MATERIAL.

This product is for use co both field and greenhals gross and onleantails. USE WON-CHRORINATED WATER AT A PHILE ART OUT THE SPRAY TAVIO MIX SPOOLX LC may be expliced up to and including the day of horvest and starage. Shake seed before using,

#### LLETED WARRANTY

Cop Genetic Franciscul makes to manaky, express or insked including the naturals of memberubility ender finess for any particular purpose, concerning the maleus (except hose which are contained on this label.

Oraș Genelice Idametional - A Subsidiiry of biospe • 10150 Clet Chlumbia Road • Chlumbia, ND 21046



SEP-03-1998

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THRMO

TRILOGY

#### PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CAOP	RAT	Ε	,
	Billions OBs Per Acre	Mis Per Acre	
igetables: matoes, lettuce, cabbage, beans, peppers, celeny, escarcie, sweet com, ias, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
ther Crops: viton, alfalfa, soybeans, peanuls, potalces, corn, wheat, vaelpotatoes, fobacco, sunflower, sugarbeets	200	100	
oriculture: rrysanthemum, gysophila, gerbera, rose, carnalion, azalea, adiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

its product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 THE SPRAY-TANK MIX. SPOO-X LC may be applied up to and including the day of harvest and storage.

#### LIMITED WARRANTY

op Genetics International makes no warranty, express or implied, including the warrantes of merchaniability and/or fitness for any ficular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin

# TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratones of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control termitats of labellar used to past

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, mestic animals, wildlife, beneficial insects and plants.

<sup>2</sup>OD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua

Active Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua 0.64% Inert Ingredients: 'This lot contains all least 2 billion OBs/mil.

#### BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the lamity Bacufowindae, subgroup A. Numerous virus particles or vinons are randomly occluded within a stein paracrystatine matrix cated a polyhedral occlusion body (OB). The vinons occluded within the OBs are the intectious units rons consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures ove 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection utimately results in ath. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virious enter the nuclei of the epitherial is faining the midgut and replicate. Virus progeny enter the himocoel and infect virtually all cell types, including hemocytes, bacheal is, fat body cells and epidermal cells. All the cells of lissues are susceptible. Assembly of virions and formation of OBs, occur only the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear molymph becomes increasingly cloudy, Another 1-2 days falser, polyhedra-shaped bodies are defected in the blood. Depending on dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, vab become fiscoid and the infegument ruptures, releasing billions of CBs.

# PPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X doc+ not reproduce in mammahan calls. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is tiguaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

# SP-07-X © LG A Liquid Concertrate Biological Insecticide for Control of Beet Armyworm

SPOD-X LC is an IVP insectional (we product) for control of the caterpillars of the best army term on field and greenhouse crops and ornamentals. Read this tabel carefully, Refer to the Technical Belletin (in Additional Guidelines for Use

ornamentals. Read this tabel carefully. Refer to the Technical Beretin for Additional Guidelines for Use

Active Polyhedral occlusion bodies (OBs) of the increase of the incr

# CAUTION STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plently of water for at least 15 minutes. If on skin, wash thoroughty with soap and water it inhaled, remove victim to health ark Apply is sportation if indexed attention if intraccin persons.

STABLESHEET TO SERSEMENT TO SERSEMENT TO SERSEMENT

EPA REGISTRATION No. 58788-7

EPA REGISTRATION No

Net Volume: Lot No. In Accordance 10150 Old Objumpia 19040 No.

# PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC AMMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear.

Long-sleeved shirt and long pants . Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE, if no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the tollet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwallers.
STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty

Containts.
STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pats. Store at temperatures below 90°F Boactivity may be impaired by storage above 90°F. Storing the product in a freezer or refragetator will ordend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticle, spray minuture or impaire that cannot be used should be disposed of on site or at an approved waste disposal facility, in accordance with Federal and local regulation.

CONTAINER DISPOSAL: Plastic container - Imple mise (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of mia a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke, Glass container - topic mise (or equivalent). Then dispose of mia sanitary landfill or by other approved State and local procedures.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its tabeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

#### **AGRICULTURAL USE REQUIREMENTS**

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval IREI) of 12 hours

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### SHAKE WELL BEFORE USING

#### PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CRIOP	R/	ΥE	y W.
	Billions OBs Per Acre	Mis Per Acre	10000
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet com, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	t00	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, com, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

#### LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or litness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

#### TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics Infernational is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect calerpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate, its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active Ingredient\* inert ingredients: Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64% 99.36%

\*This lot contains at least 2 billion OBs/ml.

#### BIOLOGICAL PROPERTIES

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only winin the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death. larvae become flaccid and the integument ruptures, releasing billions of OBs.

#### APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR, LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Raculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed. The information contained herein is based on data which are believed to be reliable, but it is understood that such information is

not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.



SPOD-X LC is an IVP (Insentinada) Virus Product) for controlard the cateroilars of the beets anyworm on field and greenhouse crops and ornamentals. Read this laber carefully. Refer to the Technical Buildin for Additional Quidelflas for Use.

for Control of Beet Armyworm

Active ingredient\* o inert ingredients?

Polyhedral occlusion bodies (OBs) at the nuclear polyhodrosis virus of Spodoptera exigua

0.64% 99.36%

\*This lot contains at least 2 billion OBs/ml

## KEEP OUT OF THE REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT

in case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water, If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation pedicitis.

ESTABLISHMENT No. 58788-MO-002

Ang. By 19 2000 Genelics Informational 3.303

EPA REGISTRATION No. 58788-7

Net Volume: Lot No.

10150 Old Columbia Road Columbia, MD 21046

#### PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray misl.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants . Shoes plus socks.

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using lobacco, or using the tollet

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters. STORAGE AND DISPOSAL: Do not contaminate water food, or feed by storage or disposal, Open dumping is prohibited. Do not re-use empty

STORAGE: Store this product in original seated container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bioactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life. PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning, if burning is allowed, stay out of smoke. Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralis • Waterproof gloves • Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough. coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### SHAKE WELL BEFORE USING

#### **PRODUCT INFORMATION - APPLICATION** Recommended Application Rates

CROP	RA Billions OBs Per Acre		
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beels, cauliflower, cucumber, broccoli, onion	200	f00	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floricutture: Chrysanthemum, gysophila, gerbera, rose, camation, azalea, platfetus, cyclamen, sainnaulia, perapium, Boyvardia	200	f00	

This product is for use on both field and greenhouse crops and omamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

#### LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

#### TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control cateroillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans. domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active	Polyhedral occlusion bodies (OBs) of the	0.64%
Ingredient*	nuclear polyhedrosis virus of Spodoptera exigua	99.36%
Inert Ingredients:	*This lot contains at least 2 billion OBs/ml.	89.36%

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculovindae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be indested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, farvae become flaccid and the infegument ruptures, releasing billions of OBs.

#### APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR, LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LS does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.



SPOD-X LC is an IVP [Inspectional Virus Product] for control of the caterpillars of the specific and greenhouse crops and ornamentals. Read this latel carefully. Refer to the Technical Billetin for Additional Guidelines for Use.

ingrediente e Inert Ingredients:

Polyhedral occlassion bodies (OBs) cothe nuclear polymedrosis virus of Spodoptera exigue \*This lot contains at least 2 billion OBs/ml

0.64% 99.36%

## KEEP OUT OF THE REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists. ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No. 58788-7

Net Volume: Lot No.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

#### PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants . Shoes plus socks. Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### **USER SAFETY RECOMMENDATION**

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters. STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90°F. Bloactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility, in accordance

CONTAINER DISPOSAL: Plastic container - triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke. Glass container - triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

#### **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of adricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions perteining to the statements on this label about personal protective equipment (PPE) and restricted entity interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coverails \* Waterproof gloves \* Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### SHAKE WELL BEFORE USING

#### PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RAT		
	Billions OBs Per Acre	Mis Per Acre	
Vegetables: Tomatoes, leituce, cabbage, beans, peppers, celery, escarcie, sweet com, peas, asparagus, beets, cauliflower, cucumber, broccelir, onon	200	100	Repeal as necessary to maintain control
Other Crops: Cotton, atfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage.

#### LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin

# TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratones of Crop Genetics International is an IVP (insectional Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans increase amongs withful penetical insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua.

Active Polyhedral occlusion bodies (QBs) of the Ingredient nuclear polyhedrosis virus of Spodoptera exigua 0.64% Inert Ingredients: 93.369

'This lot contains at least 2 billion OBs/m/.

#### BIOLOGICAL PROPERTIES

SPOD-X.LC belongs to the family Baculovindae, subgroup A. Numerous virus particles or virions are randomly occluded ... thin a protein paracrystalline matrix called a polyhedral occlusion body (DB). The virions occluded within the DBs are the infectious units Virions contact of not-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product about De kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of farval development, infection ultimately results in death. The OBs dissolve within seconds in the midgat after ingestion. The released infectious virons enter the neucle of the epithetal cells firing the midgat and replaced. Virus progeny enter the hemocole and infect virtually all cell types, including hemocytes, racheau cells fat body cells and epidemal cells. All the cells of itssues are susceptible. Assembly of virons and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of farval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemotymph becomes increasingly cloudy. Another 1-2 days taker, polyhedria-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young farvae will occur at 5-7 days after initial ingestion. Shortly after death fair are become flacood and the integriment includers, releasing billions of OBs.

# , APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates, no member of this family is known to infect vertebrates or plants. SPOD-X IC does not reproduce in mammatian cells. No adverse effect to fish, widtlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.



SPOO.X LC is an IVP (inscribing furs Product) for control of the caterplians of the book straworm on field and greenhouse crops and ornamentals. Read this label darkely. Refer to the Technical Bulley 1 addition of Specifies for Use

Polyhedral coclusion bodies (OBs) office nuclear polyhedrosis wrus of Spodoptete exitiua.

This for contains at least 2 billion OBsmit

0.64% 99.36%

# KEEP OUT OF THE REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT

in case of contact with eyes flush with plenty of water for at least 15 minutes if on skin, wash thoroughly with soap and water if inhaled, remove victim to fresh air. Apply reoprotion of indicated. Get medical attention if unitation persons.

Mig. By.
ESTABUSHMENT No. S8788-MD-002
Cross Generates, Informational

EPA REGISTRATION No. 58768-7

Not Volume Lot No Crop Genetics International 10150 Old Columbia Road Columbia, MD 21045

# PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid sinalation or contact with skin, eyes or disthing. Avoid breathing spray mist PERSONAL PROTECTIVE EQUIPMENT: Adolecators and other handlers must wear:

Long-sieeved shirt and long pants . Shoes plus socks

Follow manufacturer's instructions for cleaning and markaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toret.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty containing

STORAGE: Store this product in original sealed container in a cool, day place maccessible to children and pets. Store at temperatures below 90 F Boastinky may be impaired by storage above 90 F. Storing the product in a freezer or refrigerator will extend as shall fill - STORING DESIDER. If Workshop the Thirty and the storing the product in a freezer or refrigerator will extend a shall fill as the storing through the stor

so it is because may be impared by storage above 90°F. Storing the product in a freezer or renigerator we extend its sharing. **Last CIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pasticide, spray moture or initiate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and focal requisitions.

COMTANER DISPOSAL: Plastic container: triple rince (or equivalent) Then offer for recycling or reconditioning or purcture and dispose of in a saintary fundit, or by importation, or, if allowed by State and local authories, by burning if burning is advised say out of smoke Glass container - Ingle instell or equivalent). Then dispose of in a saintary facility of by other approved Sate and local procedure.

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as clents, soil, or water, is:

Coveralis • Waterproof gloves • Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when farvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of intested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

Fill the mix tank with desired quantity of water. Agitation should be used during mixing, if a spreader/stricker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### SHAKE WELL BEFORE USING

#### PRODUCT INFORMATION - APPLICATION

Recommended Application Rates

CROP	RA	i i	
	Billions OBs Per Acre	Mis Per Acre	
Vegetables: Tomatoes, lettuce, cabbage, beans, peppers, celery, escarcle, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control
Other Crops: Cotton, alfalfa, soybeans, peanuts, potatoes, com, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture: Chrysanthemum, gysophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals. USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX. SPOD-X LC may be applied up to and including the day of harvest and storage

#### LIMITED WARRANTY

Crop Genetics International makes no warranty, express or implied, including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

#### **TECHNICAL BULLETIN - SPOD-X LC BIOLOGICAL INSECTICIDE** PRODUCT DESCRIPTION

SPCO-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect calerpillars without harmful effects on humans. domestic animals, wildlife, beneficial insects and clants.

SPOD-X LC is a liquid concentrate, its active ingredient is the nuclear polyhedrosis virus of Spodoptera exigua

Active Ingredient\* inert ingredients: Polyhedral occlusion bodies (OBs) of the

nuclear polyhedrosis virus of Spodoptera exigua

\*This lot contains at least 2 billion OBs/ml.

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculoveridae, subgroup A. Numerous virus particles or virious are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope. The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be intective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious vinons enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible. Assembly of virions and formation of OBs occur only with? the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter. Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death. larvite become flaccid and the integument ruptures, releasing billions of OBs.

#### APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR, LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculowruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC dues not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.



SPOO-X LC is an IVP (Insection was Product) for control of the caterpillars of the beginning or mon field and greenhouse crops and ornamentals. Read this label callefully. Refer to the Technical Belletin or Addition Guilbeline Flor Use.

Active Polyhedral occlusive bodies (OBs) of the

Ingredient' Inert ingredients: \*\*

rolyhedral occusionabodies (OBs) of the 
nuclear polyhedrass virus of Spodopterasxigm 

0.64%

\*This lot contains at least 2 billion OBs/ml

## KEEP OUT OF THE REACH OF CHILDREN CAUTION STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. It on skin, wash thoroughly with soap and water, it inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists. Mfg. By:

ESTABLISHMENT No 58788-MD-002 EPA REGISTRATION No. 58788-7

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

99.76%

Net Volume: Lot No.

99.36%

# PRECAUTIONARY STATEMENTS: HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

PRECAUTIONARY STATEMENTS: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist, PERSONAL PROTECTIVE EQUIPMENT: Applicators and other handlers must wear:

Long-sleeved shirt and long pants . Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters,

STORAGE AND DISPOSAL: Do not contaminate water food, or feed by storage or disposal. Open dumping is prohibited. Do not re-use empty

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pels. Store at temperatures below 90°F. Broactivity may be impaired by storage above 90°F. Storing the product in a freezer or refrigerator will extend its shelf-life

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Pesticide, spray mixture or installe that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

CONTAINER DISPOSAL: Plastic container - Inple roise (or equivalent). Then offer for recordificating, or pureture and dispose of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning is allowed, stay out of smoke Glass container - Inpie nose (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation. (Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls • Waterproof gloves • Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this

Fill the mix tank with desired quantity of water. Aditation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### SHAKE WELL BEFORE USING



# FACSIMILE MESSAGE

TO:

Linda Hollis

DATE:

September 3, 1998

COMPANY: U.S. Environmental Protection Agency

FAX NO.:

(703) 308-7026

TOTAL PAGES: 8 15

(including cover)

FROM:

Jim Messina

MESSAGE: As instructed in your voice mail message dated September 3, 1998, please find attached a copy of the June 25, 1996 submission package, a copy of the June 26, 1996 EPA receipt form, a copy of your August 14, 1996 approval letter, and a copy of the August 27, 1996 final submission. Please note that the label and correspondence reflects Biosys, Inc. and Crop Genetics International; however, Thermo Trilogy Corporation now owns these companies and the product registrations have been officially transferred to us. The current registration number for Gemstar LC is 70051-46.

I look forward to receiving an EPA stamped approved copy of the enclosed label. If you need any additional information, please contact me at (301) 483-3812. Thank you for your help in this matter.

9145 Guilford Rd. Suite 175 Columbia, mb 21046

98%



August 27, 1996

Linda Hollis
Biopesticides and Pollution Prevention Division (7501W)
Office of Pesticide Programs
Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Continuation of Application for Label Amendments Dated June 25, 1996 - Submission of Corrected Labels per EPA Request Dated

Aug 14, 1996

SPOD-X® LC, EPA Reg. No. 58788-7

Dear Ms. Hollis:

In response to your letter dated August 14, 1996, I am submitting herein five (5) copies of the SPOD-X® labeling with the requested change. I am also enclosing a copy of your August 14 letter, and an EPA Form 8570-1 (Application for Pesticide - Other).

We appreciate your timely response to our application for these minor label amendments, and look forward to receiving a stamped copy of the label for our files.

If there are any further questions, please contact me at (410) 381-3819. Thank you again for your continued assistance.

Sincerely

David P. Miller

Manager of Regulatory Affairs

A BIOLOGICAL PEST CONTROL COMPANY

10150 OLD COLUMBIA ROAD, COLUMBIA, MD 21046-1704 • (410) 381-3800 • FAX (410) 381-3840

98%

34

Please read instructions o	n reverse before comple	ting form.			Form Appr	oved,	OMB No. 2	070-006	O, Appro	vel expires 05-31-9	
<b>\$EPA</b>	Environmental	United States nental Protection Agency Washington, DC 20450			•	X	Registration Amendment X Other			OPP Identifier Number 246011	
		Application	on for I	Pesticid	e - Sec	tion	l l				
1. Company/Product Number EPA Reg. No. 58788-7				2. EPA Product Manager Linda Rollis				3. Proposed Classification			
	4. Company/Product (Name)			PM# 90					None	Restricted	
5. Name and Address of Applicant Unclude ZIP Code)  Crop Genetics International/biosys 10150 Old Columbia Road Columbia, MD 21046  Check if this is a new address				6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name							
			Sec	tion - II							
Amendment - Explain below,  Resubmission in response to Agency letter dated  Notification - Explain below.				Final printed labels in response to Agency letter dated "Me Too" Application.  X Other - Explain below.							
August 14, 1				tion - III							
1. Material This Product			T								
Child-Resistant Packaging Yes* No	Year Year			Yos No			Glass	Metal Plastic Glasy			
Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per . container	If "Yes Pecker	s" ge wgt	No. per containe	r	Paper Other (Specify)				
J. Location of Net Conten	ta Information  Container	4. Size(s) Re	tall Contai	ner		5. Lo	Cation of La On Labe On Labe	ıl	dons mpsnying	product	
8. Manner In Which Label	6. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stendied										
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1. Contact Point (Comple	yte items directly below :	for identificati	on of indiv	idual to be	contacted,	if nec	essary, to p	rocess th	is applicat	ion.)	
i tanto			Tide Magag	Many may of Danilutory Affaire				1	ne No. (Include Area Code)		
Cartification  I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.  I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.  6. Date Application Received  (Stamped)											
Signature			3. Tiue Manager of Regulatory Affairs								
4. Typed Name	4. Typed Name 5. I							<del>-</del>	1		
David P. Hiller				ust 27,	1996						

98%



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

AUG | 4 1996

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES** 

David P. Miller Manager, Regulatory Affairs Crop Genetics International/BioSys 10150 Old Columbia Road Columbia, Maryland 21046-1274

Dear Mr. Miller:

Subject:

SPOD-X LC

EPA Reg. No. 58788-7

Application for label amendments dated 6/25/96

The labeling amendments referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended, is acceptable with the following comment.

Place the "Keep Out of Reach of Children" statement before the signal word "Caution".

Submit five (5) copies of the labeling with this change. Any further questions, contact Linda Hollis @ (703) 308-8733.

Sincerely,

Linda Hollis

Regulatory Action Leader

Biopesticides and Pollution Prevention Division

98%

7501W



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

06/26/96

DAVID P. MILLER CROP GENETICS INTERNATIONAL 10150 OLD COLUMBIA RD COLUMBIA MD 210461704 OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

PRODUCT NAME: SPOD-X LC

COMPANY NAME: CROP GENETICS INTERNATIONAL

OPP IDENTIFICATION NUMBER: 245606 EPA REGISTRATION NUMBER: 58788-7

EPA RECEIPT DATE: 06/26/96

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application qualifies for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions, please contact Phil Hutton, Product Manager 90, at (703)-308-8260.

Sincerely,

J. Wrice

Front End Processing Staff Information Services Branch Program Management and Support Division

98%



RECD EPA/UPP/DPD2

'96 JUN 26 A8:53

June 25, 1996

Phil Hutton (PM-18)
Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Minor label amendment, SPOD-X® LC Biological Insecticide, EPA

Dear Mr. Hutton:

biosys is making several minor changes to the labeling on the above-referenced product.

Attached are: (1) form 8570-1 describing the changes, (2) a copy of the previously approved, EPA-stamped label for this product, and (3) five copies of the new label copied onto 8½×11 paper. I have highlighted the changes on the first copy of the label.

As outlined on the form 8570-1, the changes in this label are:

- The restricted entry interval in the WPS section was reduced from 12 hours to 4, as was discussed at a Crop Genetics International (CGI) / EPA meeting held April 13, 1995, and attended by you, Janet Anderson, Bill Schneider, and Roy Sjoblad.
- The application rate table was modified to allow a range of use rates from the prior label rate down to half that rate.
- The section of the product label which had been referred to as the "technical bulletin" was deleted. This portion of the label had no required statements.

No new crops or insects were added, and no changes were made to required label statements other than those described above.

As you are aware, CGI was acquired by biosys early in 1995. We will soon submit the require documentation to effect a full transfer of all of CGI's registrations and supporting data to biosys.

If you should have any questions regarding this amendment, please contact me at (410) 381-3819, or via fax at (410) 381-3844

Sincerely,

David P. Miller

Manager of Regulatory Affairs

A BIOLOGICAL PEST CONTROL COMPANY



June 25, 1996

Phil Hutton (PM-18)
Office of Pesticide Programs
Document Processing Desk (AMEND)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: Minor label amendment, SPOD-X® LC Biological Insecticide, EPA

Number 58788-7

Dear Mr. Hutton:

biosys is making several minor changes to the labeling on the above-referenced product. Attached are: (1) form 8570-1 describing the changes, (2) a copy of the previously approved, EPA-stamped label for this product, and (3) five copies of the new label copied onto 8½×11 paper. I have highlighted the changes on the first copy of the label.

As outlined on the form 8570-1, the changes in this label are:

- The restricted entry interval in the WPS section was reduced from 12 hours to 4, as was discussed at a Crop Genetics International (CGI) / EPA meeting held April 13, 1995, and attended by you, Janet Anderson, Bill Schneider, and Roy Sjoblad.
- The application rate table was modified to allow a range of use rates from the prior label rate down to half that rate.
- The section of the product label which had been referred to as the "technical bulletin" was deleted. This portion of the label had no required statements.

No new crops or insects were added, and no changes were made to required label statements other than those described above.

As you are aware, CGI was acquired by biosys early in 1995. We will soon submit the require documentation to effect a full transfer of all of CGI's registrations and supporting data to biosys.

If you should have any questions regarding this amendment, please contact me at (410) 381-3819, or via fax at (410) 381-3844.

Sincerely,

David P. Miller

Manager of Regulatory Affairs

#### A BIOLOGICAL PEST CONTROL COMPANY

10150 OLD COLUMBIA ROAD, COLUMBIA, MD 21046-1704 • (410) 381-3800 • FAX (410) 381-3840

SEP-03-1998 17:49

Please read instructions on reverse before completing form.

Form Appro	ved.	OMB No. 2070-0080.	Approval expires 05-31-98
		Registration	OPP Identifier Number
	X	Amendment	245469
		Other	L-10-100

	United States				Registra	tion	OPP Identifier Number
<b>SEPA</b>	Environmental Protection Agency  Washington, DC 20460  X Amendment Other				nent	245469	
	Applicat	ion for l	Pesticide -	Section	n I		
1. Company/Product Number			2. EPA Produ	uct Manage		3. Pro	oposed Classification
	58788-7		Phil Ho	utton			None Restricted
4. Company/Product (Name) SPOD-X LC			PM# 18				
5. Name and Address of App Crop Genetics Int biosys 10150 Old Columbi Columbia MD 21046 Check if this	ary of	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name					
	Section - II						
Amendment - Explain below.  Resubmission in response to Agency letter deted							
. 3. Deleted non-	required label elemen	ts.					
		Sec	tion - III				
1. Material This Product Will	l Be Packaged In:				1		
Child-Resistant Packaging Yes* No	Unit Packaging Yes No No No. per	Water	Soluble Packe Yes No		2. Type of	Container Metel Plastic Glass Paper	
Certification must submitted	If "Yea" No. per Unit Packaging wgt. containe			No. per container		4	Specify)
3. Location of Net Contents  Label C	Information 4. Size(s) I	Retail Conta	iner	5.	Location of Lab On Label On Label		ons npanying product
6. Manner in Which Label is	Affixed to Product	ograph or glued nciled		Other _			
			tion - IV				
1. Contact Point (Complete	items directly below for identifica	Title	vidual to be co	ntected, if i	ecessary, to pr		
Name David P. Miller			ger of Reg	gulatory	Affairs		e No. (Include Area Code) B1-3800
Certifical contify that the statements I have made on this form and I acknowledge that any knowledge false or misleading state both under applicable law.							8. Date Application Received (Stamped)
nature		3. Tide	er of Regi	ulatory	Affairs		
4. Typod Name David P. Mille	er	Manager of Regulatory Affairs  5. Date 6-25-96					

98%

# THERMO TRILOGY SPOD-X LC DRAFT LABELLING Page 1 of 6

SPOD-K® LC

A Liquid Concentrate
Biological Insecticate
for Control of
Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera</u> exigua

0.64%

Inert Ingredients:

99.36%

#### KEEP OUT OF THE REACH OF CHILDREN

#### CAUTION

#### STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By:

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

ACCEPTED
WILL COMMENTS
LITEPA LOUGE Detect

MAR 02 1995

heder the Federal instability impicide, and he has side has a cmended, for the production registered under 1224 from the 58 788 - 7

98%

<sup>\*</sup>This lot contains at least 2 billion OBs/ml.

# THERMO TRILOGY SYUD-X LC DKAFI LABELLING Page 2 of 6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants

Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

#### CONTAINER DISPOSAL:

<u>Plastic container</u>—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

Glass container—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

#### Page 3 of 6

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls Waterproof gloves Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

99%

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

# THERMO TRILOGY SFOD-A LC DAAI: I LABELLING Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### PRODUCT INFORMATION

#### Application

#### Recommended Application Rates

CROP	RATE				
	Billion OBs Per Acre	Mls Per Acre			
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet com, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.		
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100			
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	. 200	100			

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A PH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

SEP-03-1998 17:51 THERMO TRILOGY

Page 5 of 6

ion of

P.14/15

TECHNICAL BULLETIN
SPOD-X LC BIOLOGICAL INSECTICIDE

days

atures,

PRODUCT DESCRIPTION

produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus d to control caterpillars of labelled insect pests.

ISTAR. ISUME

provides a unique opportunity for biological control of insect caterpillars without harmful effects omestic animals, wildlife, beneficial insects and plants.

ebrates or neficial

is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of Spodoptera

erstood

used at

lient\*

redral occlusion bodies (OBs) of the ar polyhedrosis virus of Spodoptera exigua

0.64%

ints:

99.36

: lot contains at least 2 billion OBs per ml.

#### **BIÓLOGICAL PROPERTIES**

belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are cluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are y an envelope.

is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be 0° F.

#### MODE OF ACTION

ist be ingested to be infective. When infected, at early stages of larval development, infection sults in death. The OBs dissolve within seconds in the midgut after ingestion. The released ions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the d infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells of tissues are susceptible.

99%



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

June 12, 1997

Mr. Jow-Li Su, President Thermo Triology Corporation 7500 Grace Drive Columbia, MD 21044

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Su:

Subject: Transfer of Pesticide Registrations and Data From Company Number 58788 to Company Number 70051

Pursuant to your request in your letter and transfer agreement undated (received February 10, 1997), we have approved the transfer of the following registrations and data from Crop Genetics International Corporation, company number 58788, to Thermo Triology Corporation, company number 70051.

The effective date of these changes is the date of this letter.

Registered Products	Reg. No.	Reg. No.
SPOD-X Wettable Powder	58788-1	70051-42
Gusano Biological Pesticide	58788-3	70051-43
CYD-X	58788-4	70051-44
GEMSTAR LC	58788-5	70051-45
SPOD-X LC	58788-7	70051-46

You also requested transfer of the Experimental Use Permit, 58788-EUP-1, "INCIDE". According to our records this EUP is inactive and has expired and therefore is not eligible for transfer.

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the

effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to initiation. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

In regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The marginal maintenance fee is determined based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer undated (received February 10, 1997) to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date Thermo Triology Corporation will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency 401 M Street, S.W. Washington, DC 20460-0001

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact me at (703) 305-6474.

Sincerely,

Andrew Markin

Donna G. Parker

Information Management Specialist

Information Services Branch

Information Resources & Services Div (7504C)

cc: Dr. Edwin C. Quattlebaum, President & CEO Crop Genetics International Corporation 10150 Old Columbia Road Columbia, MD 21046

OMB No. 2070-0060 Approval expires 2-28-95

Please road instructions on reverse before completing form.	Form	Approved OMR No. 3	O70-0060. Approval expires 2-28-5				
United States Environmental Protect Washington, DC 20	ion Agency	x Registra Amenda Other	tion OPP Identifier Number				
Applicat	ion for Pesticide - Se	ection I					
1. Company/Product Number 58788–7	2. EPA Product N Phil He	~	3. Proposed Classification				
4. Company/Product (Name) SPOD-X <sup>R</sup> LC	PM# 18		X None Restricted				
5. Name and Address of Applicant (Include ZIP Code)  Crop Genetics International 10150 Old Columbia Road Columbia, Maryland 21046  Check if this is a new address	(b)(i), my producto:	EPA Reg. No					
	Section - II	·					
Amendment - Explain below.  Resubmission: in response to Agency letter dated  Notification - Explain below.  Explanation: Use additional page(s) if necessary. (For sections)	Agency "Me Too	nted labels in response letter dated " Application. Explain below.	to March 2, 1995				
	Section - III						
Material This Product Will Be Packaged In:							
Child-Resistant Packaging  Yes* No  If "Yes" Unit Packaging  No. per Unit Packaging  No. per Unit Packaging  Yes  No. per Container	Water Soluble Packaging Yes No If "Yes" No. p. Package wgt Conta		Container  Metal Plastic Glass Paper Other (Specify)				
3. Location of Net Contents Information 4. Size(s) Roll Label Container	etail Container	5. Location of Lab On Label On Labeli	el Directions ng accompanying product				
6. Manner in Which Label is Affixed to Product Litho Pape Sten	ograph Or r glued ciled	ther					
	Section - IV						
1. Contact Point (Complete items directly below for identification	ion of individual to be contact	ed, if necessary, to pro	ocess this application.)				
Name R. Mark Beach	Title Director, Product	Title Telephone No. (Include Area Co Director, Product Development 410-381-3800					
Certific I certify that the statements I have made on this form an I acknowledge that any knowingly false or misleading sta both under applicable law.	d all attachments thereto are						
2. Signature Reach Beach	3. Title  Director, Produc	t Development	••••				

5. Date

April 28, 1995

4. Typed Name

R. Mark Beach



#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152,81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);

- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted of x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.

  Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.

  Makage-the size of the individual packets and number per retail container.
- 2. Type of Retail Centainer Indicate type of container in which product will be marketed.
- 3. Leannies of Net Cantegra Indicate the location of the net contents information for your product.
- 4. Sixel of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which labeles affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Centect Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

	EPA REGISTRATION NO.	DATE OF ISSUANCE
US ENVIRONMENTAL PROTECTION AGENCY	58788-7	DATE OF ISSUANCE
OFFICE OF PESTICIDES PROGRAMS REGISTRATION DIVISION (TS-767) WASHINGTON, DC 20460	TERM OF ISSUANCE	MAR 0 2 1995
NOTICE OF PESTICIDE: REGISTRATION REREGISTRATION	NAME OF PESTICIDE PROD	UCT
(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)	SPOD-X <sup>R</sup> LC	
NAME AND ADDRESS OF REGISTRANT (Include ZIP code)		
	a a	
CROP GENETICS INTERNATIONAL 10150 Old Columbia Raad Columbia, Maryland 21046		
L.	. Т	
NOTE: Changes in labeling formula differing in substance fr submitted to and accepted by the Registration Division prior product always refer to the above U.S. EPA registration num	to use of the label in comme	erce. In any correspondence on this
On the basis of information furnished by the registrant, the a the Federal Insecticide, Fungicide, and Rodenticide Act.	above named pesticide is her	eby Registered/Reregistered under
A copy of the labeling accepted in connection with this Reg	istration/Reregistration is r	eturned herewith.
Registration is in no way to be construed as an indorsement health and the environment, the Administrator, on his motion icide in accordance with the Act. The acceptance of any nat Act is not to be construed as giving the registrant a right to by others.	n, may at any time suspend o me in connection with the rep	r cancel the registration of a pest- gistration of a product under this
This product is <b>uondádional</b> ally re 3(c)(7)(A) provided that you:	gistered in accordan	ce with FIFRA sec.
1. Submit and/or cite all data require product under FIFRa sec. 3(c) \$5) when t similar products to shbmit such data; a for reregistration of your product under the state of the should be such as the second secon	he Agency requires al nd submit acceptable	ll registrants of
The second secon		
<ol> <li>Make the following label changes: Rebise the EPA Registration Number</li> </ol>	to read "58788-7"	Service of the servic
ATTACHMENT IS APPLICABLE		
SIGNATURE OF APPROVING OFFICIAL		DATE
i to a limit with	7 3 17 3	I was I I was a

#### SPOD-X LC DRAFT LABELLING Page 1 of 6

SPOD-X® LC

A Liquid Concentrate Biological Insecticide for Control of Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera</u> exigua

0.64%

Inert Ingredients:

99.36%

\*This lot contains at least 2 billion OBs/ml.

#### KEEP OUT OF THE REACH OF CHILDREN

#### **CAUTION**

#### STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By:

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

ACCEPTED
with COMMENTS
to EPA Letter Detect

MAR 0-2 1995

the for the Reciprof Proving to the Salar and Reciprof to Are a marked, for the analysis of the Salar No. 58788-7

#### SPOD-X LC DRAFT LABELLING Page 2 of 6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

#### CONTAINER DISPOSAL:

<u>Plastic container</u>—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

<u>Glass</u> <u>container</u>—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

#### SPOD-X LC DRAFT LABELLING Page 3 of 6

#### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

#### **GENERAL INFORMATION**

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

#### SPOD-X LC DRAFT LABELLING Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### PRODUCT INFORMATION

#### Application

#### Recommended Application Rates

CROP	RATE				
	Billion OBs Per Acre	Mls Per Acre			
Vegetables	200	100	Repeat as necessary to		
Tomatoes, lettuce, cabbage, beans,			maintain control.		
peppers, celery, escarole, sweet corn,					
peas, asparagus, beets, cauliflower,					
cucumber, broccoli, onion					
Other Crops	200	100			
Cotton, alfalfa, soybeans, peanuts,			N.		
potatoes, corn, wheat, sweetpotatoes,					
tobacco, sunflower, sugarbeets					
Floriculture	200	100			
Chrysanthemum, gypsophila, gerbera,					
rose, carnation, azalea, gladiolus,					
cyclamen, saintpaulia, geranium,					
Bouvardia					

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

#### SPOD-X LC DRAFT LABELLING Page 5 of 6

### TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of <a href="Spodoptera">Spodoptera</a> exigua.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>

0.64%

Inert Ingredients:

99.36

\*This lot contains at least 2 billion OBs per ml.

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

#### SPOD-X LC DRAFT LABELLING Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046



### **CROP GENETICS INTERNATIONAL**

10150 OLD COLUMBIA ROAD COLUMBIA, MD 21046-1704

PHONE: (410)381-3800 FAX: (410)381-3840

ATTENTION: COMPANY: FAX NUMBER:	Linda Hollis EPA  403-308-4026	
FROM:	Mark Beach	
DATE: TOTAL PAGES:	2/2 <u>+/95</u> -3	4.

58788-T

MESSAGE:

The MRID # is 4353750/ as per attached

FEB 1 0 1995

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

CROP GENETICS INTERNATIONAL 10150 OLD COLUMBIA ROAD COLUMBIA, MD 21046

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/07/95. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

435375-()

#### TRANSMITTAL DOCUMENT

#### NAME AND ADDRESS OF SUBMITTER

Crop Genetics Antil 10150 Old Columbia Rd Columbia, MD 21046

application to amend pending registration

DATE RECEIVED BY EPA

2/7/95

LIST OF SUBMITTED STUDIES:

Supplement to Spool - X LC Product Chemistry; 58788-T; Guidelino 151A-15

FOR ISB USE

Date to ISB:

Company No.:

Reg. No.(s):

Date to Index:

Guideline:

Date frm Indx:

Page Count:

Addressee:

Groundwater? State(s):

Notify:

Chem. Name(s) & Code(s):

Category: 1) 6a2 2) adv. flag

Please	read	instru	ctions	on	reverse	before	complet	ina foi	m
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#### United States

Form App	rovec	i. OMB No. 2070-0060	. Approval expires 2-28-95
	¥	Registration	OPP Identifier Number
		Amendment	238310
	X	Other	200010

Environmental Protection Washington, DC	Amendme X Other	nt 238310					
Applica	tion for Pesticide - Sec	tion I					
1. Company/Product Number 58788-T	Phil Hutton	2. EPA Product Manager Phil Hutton					
4. Company/Product (Name) Spod-X LC	PM# 18		X None Restricted				
5. Name and Address of Applicant (Include ZIP Code)  Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046  Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No.  Product Name						
Agent to see adequate which displays an extract company and the control and th	Section - II						
Amendment - Explain below.  Resubmission in response to Agency letter dated							
Explanation: Use additional page(s) if necessary. (For section I and Section II.)  Revised CSF and Five batch analysis per EPA letter dated 2/3/95							
	Section - III						
1. Material This Product Will Be Packaged In:							
Child-Resistant Packaging  Yes* No  * Certification must be submitted  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.  No. per Container	Water Soluble Packaging  Yes  No  If "Yes"  No. per Package wgt  containe	Yes Metal Plastic Glass If "Yes" No. per Paper					
3. Location of Net Contents Information 4. Size(s) F  Label Container	Retail Container	5. Location of Label D On Label On Labeling	irections accompanying product				
6. Manner in Which Label is Affixed to Product Lith Pap Stell	ograph Othe						
	Section - IV						
1. Contact Point   Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)  Name James H. Davis  Title Vice President  (410) 381-3800							
Certifi I certify that the statements I have made on this form a I acknowledge that any knowingly false or misleading st both under applicable law.	nd all attachments thereto are true, accurate and complete. Received						
2 Signatur James HD_	3. Title Vice President						
4. Typed Name James H. Davis	5. Date 02/06/95						

435375-01

Title

Supplement to Spod-X® LC - Product Chemistry

Volume Number

II of II

Data Requirement

Pesticide Assessment Guidelines Subdivision M, Guideline #151A-15

EPA's File Symbol

58788-T

**Author** 

R. Mark Beach

Completed On:

February 6, 1995

Performing Laboratory

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046 (410) 381-3800

#### STATEMENT OF DATA CONFIDENTIALITY CLAIMS

Information claimed confidential on the basis of its falling within the scope of FIFRA §10 (d) (1) (A), (B), or (C) has been removed to a confidential appendix and is cited by cross-reference number in the body of the study.

Company:

Crop Genetics International

Company Agent:

James H. Davis

Title:

Vice President

Signature

2/6/95

Date

#### GOOD LABORATORY PRACTICE STATEMENT

EPA's Good Laboratory Practice Standards (40 CFR 160; Fed. Reg. 34052, August 17, 1989) do not apply to Pesticide Assessment Guideline Number 151A-15.

### Place Holder Page

This place holder page is inserted in place of all pages found in the confidential attachment.

Cross Reference  $\underline{1}$ 151A-15 Certification of Ingredient Limits Pages 66-68 - \*Access to FIFRA health and safety data is restricted under FIFRA section  $10(g)^*$ 

#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB 03 1995

170 15471605 Hollis

James H. Davis
Vice President of Research
and Development
Crop Genetics International
10150 Old Columbia Road
Columbia, MD. 21046

Subject: Spod-X LC

EPA File Symbol 58788-T

Dear Mr. Davis:

The submission referred to above, submitted in connection with registration under FIFRA as amended will be acceptable when you submit the following:

1. Submit a revised CSF and a five batch analysis expressing the total number of occlusion bodies in the preparation.

Sincerely,

Janet L. Andersen, Acting Director Biopesticides and Pollution Prevention Division

CONCURRENCES								
SYMBOL	750/W	TSOIN						
SURNAME	tollis	a. Char			*****************			•••••
DATE	42195	36655					******	
	OFFICIAL FUE COPY							

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

\*U.S. GPO: 1975-503/82085

Please read instructions on reverse before completing form.	Form Ap	proved. OMB No. 2070-006	O. Approval expires 2-28-95									
United States Environmental Protecti Washington, DC 20	ion Agency 0460	Registration Amendment  Other										
Applicati	ion for Pesticide - Sec	tion I										
1. Company/Product Number 58788-T	2. EPA Product Mar	·ton —	roposed Classification									
4. Company/Product (Name) Spod-X LC	PM# 18	1 PM# 1 1 4 1										
5. Name and Address of Applicant (Include ZIP Code) Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046	(b)(i), my product to:	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:  EPA Reg. No										
Check if this is a new address	Product Name	Product Name										
Section - II												
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Agency let	Final printed labels in response to Agency letter dated "Me Too" Application.  X Other - Explain below.										
Explanation: Use additional page(s) if necessary. (For section I and Section II.)  Forms 8570-20 and 8570-29 submitted herewith per request.												
	Section - III											
Material This Product Will Be Packaged In:												
Child-Resistant Packaging  Yes* No  * Certification must be submitted  Unit Packaging  Yes  No  If "Yes" Unit Packaging wgt.  No. per container	Water Soluble Packaging  Yes  No  If "Yes"  No. per Package wgt  Containe	2. Type of Container  Metal Plastic Glass Paper Other (S	Metal Plastic Glass									
	etail Container	5. Location of Label Direction	~~~									
Label Container		On Label On Labeling accom										
6. Manner in Which Label is Affixed to Product Lithographer	graph Othe r glued ciled	) <b>r</b>										
Stenc	Section - IV		0.000									
Contact Point		if nacaceany to procees this	annimation 1									
Name James H. Davis	Title Vice President	Telephon	application.)  is No. (Include Area Than)  381-3800									
Certifica I certify that the statements I have made on this form and I acknowledge that any knowingly false or misleading state both under applicable law.	d all attachments thereto ere tru	•	6. Date Application Received (Stamped)									
2. Signature	3. Title  Vice President	0 000										
4. Typed Name James H. Davis	5. Date 1/10/95											

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4):
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a
  basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable-amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Leastion of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

United States

#### Environmental Protection Agency

Form Approved OMB No. 2070-0060

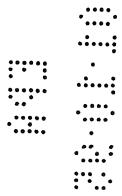
#### Approval Expires 02-28-95 Washington, DC 20460 Certification with Respect to Citation of Data EPA File Symbol/Registration Number 58788-TA Applicants Name and Address Crop Genetics Intenational Spod-XR LC 10150 Old Columbia Rd, 21046 Columbia, MD Date of Application July 21, 1994 NOTE: If your product is a 100% repackaging of another EPA-registered product that you purchase, and is labeled for the same uses, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27). 1. This application is supported by all data submitted or cited in the application. In addition, if cite-all options are indicated, this application is supported by all data in the Agency's files that concern the properties or effects of this product that is identical or substantially similar and that is one of the types of data that would be required to be submitted if this application sought the initial registration of a product of identical or similar composition and intended uses under the data requirements in effect on the date of approval of this application. (Check the appropriate boxes, in items 2 and 3, or 4 below that pertain to your application.) 2. I certify that, for each study cited in support of this application for registration that is an exclusive use study. I am the original submitter\*; or I have obtained the written permission of the original submitter for which is (insert name of chemical) (for multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\* 3. I certify that, for each study cited in support of this application for registration that is not an exclusive use study; I am the original data submitter\*; or I have obtained the written permission of the original data submitter for (for multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study\*; or I have notified in writing the companies that (insert names of companies) (insert name of chemical) have submitted data I have cited to support this application and have offered to: (a) Pay compensation for those data in accordance with section 3(c)(1)(F) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); and (b) Commence negotiations to determine which data are subject to the compensation requirement of FIFRA and the amount and terms of compensation due, if any. The companies I have notified are: Companies (for multiple (insert names of companies) (insert name of chemical) chemicals link the companies who are original data submitters with the appropriate chemical name) listed on the Pesticide Data Submitters List for all active ingredients contained in my product (cite-all method or cite-all option under Selective Method\*). (Also, sign the General Offer Statement below.) Companies (for multip (insert names of companies) (insert name of chemical) chemicals link the companies who are original data submitters with the appropriate chemical name, that have submitted the studies which I have cited (Selective method\*). I certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive use and data compensation have expired. \* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method) Name and Title James H. Davis, Vice President Date January 6: 1995 Signature General Offer to Pay: Thereby offer and agree to pay compensation to other persons, regard to the approval of this application, to the extent required.

Name and Title

Signature

#### Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W., Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055), Washington, DC 20503, marked "Attention Desk Officer for EPA."



**SEPA** 

## U.S. ENVIRO MENTAL PROTECTION AGENCY REGISTRATION DIVISION (TS-767) WASHINGTON, D.C. 20460

#### **DATA REFERENCE SHEET**

(See instructions on the back of the last page before completing.)

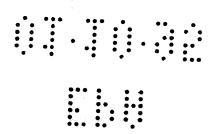
1 OF 2

2. EPA REGISTRATION NO./FILE
SYMBOL 58788-TA

Crop Genetics International 10150 Old Columbia Rd.  Spod- 5. PROD			d-X LC DDUCT MANAGER  1 Hutton, PM 18  G TO ACCOMPANY APPL FOR REGISTRATION C July 21, 1994				LICA DAT	TION ED:	1			
SOURCE OF STUDY								_				
7. NAME OF STUDY	a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE d. PU		d, OBTAINED FROM PUBLIC LITERATURE (give reference)	e, OTHER (explain)		f. ACCESSION NUMBER (if known)				
151A10-17 Product Chemistry	Х											
152A-10 Acute Oral Toxicity/Pathogenicity					Referenced in Data Waiver Request			المساومة مرزة المقاريمي المساومة				
152A-11 Acute Dermal Toxicity					Referenced in Data Waiver Request							
152A-12 Acute Pulmonary Toxicity/Pathogenicity					Referenced in Data Waiver Request							
Intraperitoneal Injecti Toxicity/Pathogenicity												
152A-14 Primary Eye Irritation					Referenced in Data Waiver Request							
152A-15 Hypersensitivity Incidents					Referenced in Data Waiver Request							
152A-16 Cell Culture	Х											
Tier II, Tier III Toxicity Studies	•••				Referenced in Data Waiver Request							
154A-16 Avian Oral Toxicity	•				Referenced in Data Waiver Request							
	K	If yo	bu marked "X" in this column, do you wish you on the Data Submitters List?	our nam	e TYES							

BURDEN STATEMENT FOR DATA REFERENCE SHEET (EPA Form 8570-20; OMB Form No. 0070-0060)

The public reporting burden for this collection of information is estimated to average one hour per completed Data Reference Sheet. This includes reviewing instructions, identifying pertinent references, and citing the references on this instrument. It is estimated that approximately eight (8) hours are required to prepare a complete set of references for an initial application to register a "typical" or "average" chemical. After that, additional supporting references may be necessary but would not require the number of references necessary for an initial application to register. Send comments regarding this burden, to: Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0060), Washington, DC 20503



**SEPA** 

#### U.S. ENVIRONMENTAL PROTECTION AGENCY REGISTRATION DIVISION (TS-767) WASHINGTON, D.C. 20460

#### DATA REFERENCE SHEET

(See instructions on the back of the last page before completing.)

2 OF 2

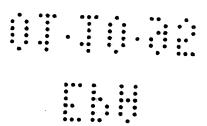
2. EPA REGISTRATION NO./FILE
SYMBOL

58788-T

Crop Genetics Interna	tion	o 1		Spod-	X LC						Į
10150 Old Columbia Rd.,			5. PRODUCT MANAGER  6. TO ACCOMPANY APPLIFOR REGISTRATION D					CATI	ON		
l l			Phil Hutton, PM 18 July 21,					S .			
SOURCE OF STUDY									***************************************		
7. NAME OF STUDY	a. APPLICANT CONDUCTED STUDY (mark 'X')	b. OBTAINED FROM EPA (mark 'X')	c. OBTAINED FROM ANOTHER FIRM OR SOURCE (give name and address)		d. OBTAINED FROM PUBLIC LITERATURE (give reference)	e. OTHER (explain)		f. ACCESSION NUMBER (if known)			
154A-14 Freshwater Fish Test					Referenced in Data Waiver Request						
154A-20 Freshwater Aquati Invertebrate Test					Referenced in Data Waiver Request	and the second seco	MATERIAL PROPERTY AND				
154A-21 Estuarine and Marine Animal Tests					Referenced in Data Waiver Request						
154A-22 Nontarget Plant Studies					Referenced in Data Waiver Request						
154A-23 Nontarget Insect Studies					Referenced in Data Waiver Request						
154A-24 Honeybee Tests					Referenced in Data Waiver Request						
					ANG:						
	•••	•									
	•		·	AND THE SECOND S							
	K	If yo	ou marked ''X'' in this column, do you wish yed on the Data Submitters List?	our nam	e YES			118,0			

BURDEN STATEMENT FOR DATA REFERENCE SHEET (EPA Form 8570-20; OMB Form No. 0070-0060)

The public reporting burden for this collection of information is estimated to average one hour per completed Data Reference This includes reviewing instructions, identifying pertinent references, and citing the references on this It is estimated that approximately eight (8) instrument. hours are required to prepare a complete set of references for an initial application to register a "typical" or "average" chemical. After that, additional supporting references may be necessary but would not require the number of references necessary for an initial application to register. comments regarding this burden, to: Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0060), Washington, DC 20503





10150 OLD COLUMBIA ROAD COLUMBIA MD 21046-1704 USA TEL 410 381 3800 FAX 410 381 3840

October 31, 1994

#### BY HAND

Janet Andersen
Director, Biological Pollution Prevention Division
Office of Pesticide Programs
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia

RE: Pending Spod-X®LC Registration - No. 58788-T

Dear Ms. Andersen:

At the meeting you held last month with representatives of the Biotechnology Industry Organization ("BIO"), you indicated your interest in insuring not only that biological products were registered, but also that they were actually used in the agricultural community. We share your interest and are actively developing a range of insecticidal virus products for sale in the United States and overseas.

One product that we have focused on extensively is the Spod-X insecticidal virus for control of the beet armyworm on cotton, vegetables and greenhouse crops. A wettable powder formulation of this product is already registered with EPA. Since registering this product, we have developed a liquid formulation that has enhanced shelf-life stability and greater grower acceptance. This liquid formulation is currently being sold in the Netherlands in the greenhouse market where it has gained rapid market acceptance due to its high efficacy.

CGI desires to begin selling this liquid formulation in the United States next summer for control of beet armyworm on cotton and vegetables. As you may know, current products being sold do not adequately control this pest, and last summer several Section 18 emergency exemption requests were filed for the use of unregistered chemical products. We believe that we have a product that will meet the farmers' needs and we have the production capacity to supply the product.

What we lack is an approved label for the liquid formulation. In July of this year, we submitted an application for the new formulation - No. 58788-T. The only difference between the liquid formulation and the already approved formulation is the addition of an

Janet Andersen, Director October 31, 1994 Page 2

inert that is listed on EPA's recently published list of Minimal Risk Inerts. Thus there are not any toxicology or environmental issues associated with the new formulation.

For CGI to be in a position to market this product next summer, it is essential that CGI obtain approval for this formulation as soon as possible. This is the first product we will market in the United States. We need to have sufficient time to print final labels, to package product and distribute it to dealers, to obtain and publish advertising, and to complete the myriad of tasks necessary for successful market entrance. While these tasks may be routine for large chemical companies, they are not for us. Many of these tasks can not be completed until we have a final label.

CGI would appreciate any help that you can provide in expediting this registration. Ideally, these types of formulation changes involving inerts of no toxicological significance should be approved in a matter of weeks not months. I know this is one of your goals for the new division. Unfortunately, if CGI is to be able to supply cotton farmers with adequate beet armyworm control next summer, we can not wait for the new division to be up and running at full speed.

I will call you next week to discuss with you CGI's pending registration. If a meeting would be appropriate, I would be happy to meet with you at any time. In the meantime if you need any additional information, please call me at 410 -381-3803.

Thank you for your attention to this matter.

Sincerely,

James H. Davis

Vice President of Research

and Development

cc: Stephen L. Johnson Phillip O. Hutton



10150 OLD COLUMBIA ROAD COLUMBIA MD 21046-1704 USA TEL 410 381 3800 FAX 410 381 3840

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REGISTRATION DIVISION H-7505C

5/31/4

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October 31, 1994

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Phillip O. Hutton

Please read Instructions on reverse	e before completing form.	Form Apon	oved, OMB No 2070	0-0060, Approval expires11-30-9		
(A) SEPA	United States Environmental Pro Office of Pesticide Programs Washington, DC 204 Application for P	tection Agency (H7505C)	Registrati Amendme	ion OPP Identifier Number		
	Section					
Company/Product Number		2. EPA Product Mana	ager	3. Proposed Classification		
58788- T		Phil Hutton  PM#  X None Restricte				
Company/Product (Name)		PM# Restrict				
Spod - X LC		#18				
5. Name and Address of Applicant (In Crop Genetics Intern 10150 Old Columbia R Columbia, Maryland	ational oad 21046			e with FIFRA Section 3(c)(3) Il in composition and labeling		
Check if this is a new a	ddress	Product Name	<u> </u>			
	Section I					
Amendment - Explain below		Final printed la	bels in response to	****		
Resubmission in response to Age	ncy letter dated	"Me Too" Application.				
Notification - Explain below.		X Other - explain below.				
Explanation: Use additional page(s	if necessary /For section Land	Section II )				
			ers (comments sylvas trons y comments sylvas sylvas comments comments sylvas sylvas sylvas sylvas sylvas sylvas			
Material This Product Will Be Pac	Section III		COLUMN TO THE TOTAL PROPERTY OF THE TOTAL PR			
Child-Resistant Packaging   Unit Pack		r Soluble Packaging	2. Type of Cor	ntainer		
Yes* Yes No		Yes	X Pla	etal astic ass		
* Certification must be Unit Pack	No. per If "Ye	s," No. pe	r I Hot	per her (Specify)		
* Certification must be Submitted.	ago wg Comamor   Ago	ige wgt. Coman				
B. Location of Net Contents Information	4. Size(s) of Retail C	Ogal, 5.0 gall	5. Location of Label  X On Label	Directions		
X Label Container 0.01ga1, 0.13ga1, 0.5ga1 On Labeling accompanying product						
. Hamor in trinon again to things to	X Paper glued Stenciled	Other	(			
	Section I\					
Contact Point (Complete items directlems)	tly below for identification of indi	vidual to be contacted, if		ess this application』 phone No. (Include Area Code		
Name	erue			e i		
James H. Davis	Vice	President	. 4	10-381-3806		
I certify that the statements I have m acknowledge that any knowingly for both under applicable law.				(Stamped)		
2. Signature	3. Title			••••		
Vames HD-	Vice	President		•••		
4. Typed Name	5. Date	<u></u>		4		

James H. Davis

July 21, 1994

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];

Confidential Statement of Formula (EPA Form 8570-4);
 Formulator's Exemption Statement (EPA Form 8570-27);

4. Five copies of draft labeling;

5. Three copies of any data submitted;

6. Authorization letter where applicable;

7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

<u>SECTION I</u> - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is <u>not to be</u> used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Cheek the appropriate block if your product will be packaged in the indicated packaging types.

Indicate the size of the individual packets and number per retail container.

Type of Retail Container - Indicate type of container in which product will be marketed.
 Location of Met Contents - Specify the net contents of all retail containers for your product.

- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
  5. Location of Use Directions Indicate the location of the use directions for your product.

6. Manner in which label is affixed to product - Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

1-5. Self-explanatory. 6. EPA Use Only.

# Page 86 \*Confidential Statement of Formula may be entitled to confidential treatment\*



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

July 25, 1994

CROP GENETICS INTERNATIONAL ATTN: JAMES H. DAVIS 10150 OLD COLUMBIA RD COLUMBIA, MD 21046

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PRODUCT NAME: SPOD x<sup>R</sup>LC

COMPANY NAME: CROP GENETICS INTERNATIONAL

OPP IDENTIFICATION NUMBER: 186786 EPA FILE SYMBOL: 58788-T EPA RECEIPT DATE: 07/22/94

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for a new registration and it has passed an administrative screen for completeness.

The package will now be forwarded to the Product Manager for review to determine its acceptability.

If you have any questions please contact Phil Hutton Product Manager 18 , at (703)305-7690.

Sincerely,

Front End Processing Staff Information Services Branch

Program Management and Support Division



10150 OLD COLUMBIA ROAD COLUMBIA MD 21046-1704 USA TEL 410 381 3800 FAX 410 381 3840

BY HAND

July 21, 1994

Office of Pesticide Programs
Environmental Protection Agency
Document Processing Desk (APPL)
Room 266A, Crystal Mall #2,
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Philip Hutton, PM18

Re: New Product Registration Application for Spod-X® LC EPA Symbol 58788

Dear Mr. Hutton:

Crop Genetics International respectfully submits the following application for a new formulation of its Spod-X® bioinsecticide for control of beet armyworm. This liquid formulation is targeted, among other things, for the control of beet armyworm in cotton. Subject to regulatory approval, Crop Genetics would expect to sell this product next summer in the United States. A similar formulation (differing only in the concentration of the active ingredient) is already being sold in the Netherlands for control of beet armyworm on greenhouse crops.

Accordingly, enclosed are:

Volume I Administrative Materials

Application for Pesticide Registration (EPA Form 8570-1)

Confidential Statement of Formula

Five copies of a draft Label

Volume II(a) Spod-X® LC Product Chemistry - Guidelines #151A-10 through 151A-15, 151A-17

(b) Spod-X® LC Product Chemistry - Guideline #151A-16.

Please do not hesitate to contact me if you have any questions about the submitted package or any other issues related to the registration of Spod-X LC.

Sincerely,

James H. Davis

Vice President of Research

& Development



10150 OLD COLUMBIA ROAD COLUMBIA MO 21046-1704 USA TEL 410 381 3800 FAX 410 381 3840 BY HAND

July 21, 1994

file Stamp Copy

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Vice President of Research

& Development



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Vice President of Research

& Development

## SPOD-X LC DRAFT LABELLING Page 1 of 6

SPOD-X® LC

A Liquid Concentrate Biological Insecticide for Control of Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera</u> exigua

0.64%

Inert Ingredients:

99.36%

\*This lot contains at least 2 billion OBs/ml.

## KEEP OUT OF THE REACH OF CHILDREN

#### **CAUTION**

## STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By:

Crop Genetics International 10150 Old Columbia Road

Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

## SPOD-X LC DRAFT LABELLING Page 2 of 6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

#### CONTAINER DISPOSAL:

<u>Plastic container</u>—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

<u>Glass container</u>—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

## SPOD-X LC DRAFT LABELLING Page 3 of 6

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

#### AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

## SPOD-X LC DRAFT LABELLING Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### PRODUCT INFORMATION

## Application

## Recommended Application Rates

CROP	RATE				
	Billion OBs Per Acre	Mls Per Acre			
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.		
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100			
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100			

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

## SPOD-X LC DRAFT LABELLING Page 5 of 6

## TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of <a href="Spodoptera">Spodoptera</a> exigua.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64%

Inert Ingredients:

99.36

\*This lot contains at least 2 billion OBs per ml.

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

## SPOD-X LC DRAFT LABELLING Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

## SPOD-X LC DRAFT LABELLING Page 1 of 6

#### SPOD-X® LC

A Liquid Concentrate Biological Insecticide for Control of Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera</u> exigua

0.64%

Inert Ingredients:

<u>99.36</u>%

\*This lot contains at least 2 billion OBs/ml.

## KEEP OUT OF THE REACH OF CHILDREN

#### **CAUTION**

## STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By:

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

## SPOD-X LC DRAFT LABELLING Page 2 of 6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

#### CONTAINER DISPOSAL:

<u>Plastic container</u>—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

<u>Glass container</u>—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

## SPOD-X LC DRAFT LABELLING Page 3 of 6

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

## SPOD-X LC DRAFT LABELLING Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### PRODUCT INFORMATION

## Application

## Recommended Application Rates

CROP	RATE				
	Billion OBs Per Acre	Mls Per Acre			
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.		
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100			
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100			

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

## SPOD-X LC DRAFT LABELLING Page 5 of 6

# TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera exigua</u>

0.64%

Inert Ingredients:

99.36

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

<sup>\*</sup>This lot contains at least 2 billion OBs per ml.

## SPOD-X LC DRAFT LABELLING Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

## SPOD-X LC DRAFT LABELLING Page 1 of 6

#### SPOD-X® LC

A Liquid Concentrate Biological Insecticide for Control of Beet armyworm

SPOD-X LC is an IVP (Insecticidal Virus Product) for control of the caterpillars of the beet armyworm on field and greenhouse crops and ornamentals. Read this label carefully. Refer to the Technical Bulletin for Additional Guidelines for Use.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of <u>Spodoptera</u> exigua

0.64%

Inert Ingredients:

99.36%

\*This lot contains at least 2 billion OBs/ml.

#### KEEP OUT OF THE REACH OF CHILDREN

#### **CAUTION**

#### STATEMENT OF PRACTICAL TREATMENT

In case of contact with eyes flush with plenty of water for at least 15 minutes. If on skin, wash thoroughly with soap and water. If inhaled, remove victim to fresh air. Apply respiration if indicated. Get medical attention if irritation persists.

Mfg. By:

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046

ESTABLISHMENT No. 58788-MD-002

EPA REGISTRATION No.

Net Volume:

Lot No.

## SPOD-X LC DRAFT LABELLING Page 2 of 6

# PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS)

Precautionary Statements: Avoid inhalation or contact with skin, eyes or clothing. Avoid breathing spray mist.

Personal Protective Equipment: Applicators and other handlers must wear Long-sleeved shirt and long pants
Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

#### USER SAFETY RECOMMENDATION

Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

#### **ENVIRONMENTAL HAZARDS**

Do not contaminate water when disposing of equipment washwaters.

#### STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal. Open dumping is prohibited. Do not reuse empty containers.

STORAGE: Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 90° F.

Bioactivity may be impaired by storage above 90° F. Storing the product in a freezer or refrigerator will extend its shelf-life.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Pesticide, spray mixture or rinsate that cannot be used should be disposed of on site or at an approved waste disposal facility in accordance with Federal and local regulations.

#### CONTAINER DISPOSAL:

<u>Plastic container</u>—triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by State and local authorities, by burning. If burning is allowed, stay out of smoke.

<u>Glass container</u>—triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

## SPOD-X LC DRAFT LABELLING Page 3 of 6

## **DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

(Refer to Technical Bulletin for Additional Guidelines for Use.)

## AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

Coveralls

Waterproof gloves

Shoes plus socks

#### GENERAL INFORMATION

SPOD-X LC is a highly selective insecticide for use against the insects and on the crops listed on this label. Always follow these directions:

Treat when larvae are young (early instars) and are actively feeding. Apply before extensive damage has occurred. When insect infestations are heavy, use the higher label rates.

Thorough spray coverage is essential for good insect control. SPOD-X LC should be applied by conventional ground or aerial application equipment with quantities of water to provide thorough coverage of infested plants without runoff. The amount of water needed per acre will depend on weather, spray equipment, and local experience. Generally, use the recommended amount of SPOD-X LC in 20-100 gallons of water per acre for ground application and in at least 5 gallons of water for aerial application.

A spreader/sticker and ultraviolet screening agent may enhance the performance of this product.

## SPOD-X LC DRAFT LABELLING Page 4 of 6

Fill the mix tank with desired quantity of water. Agitation should be used during mixing. If a spreader/sticker or ultra-violet screen is used, add prior to the addition of SPOD-X LC. Mixing time can be reduced by premixing SPOD-X LC with a small amount of water and vigorously agitating before adding to the tank. Final formulation should be mixed for 10-30 minutes.

#### PRODUCT INFORMATION

## Application

## Recommended Application Rates

CROP	RATE		
	Billion OBs Per Acre	Mls Per Acre	
Vegetables Tomatoes, lettuce, cabbage, beans, peppers, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion	200	100	Repeat as necessary to maintain control.
Other Crops Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweetpotatoes, tobacco, sunflower, sugarbeets	200	100	
Floriculture Chrysanthemum, gypsophila, gerbera, rose, carnation, azalea, gladiolus, cyclamen, saintpaulia, geranium, Bouvardia	200	100	

This product is for use on both field and greenhouse crops and ornamentals.

USE NON-CHLORINATED WATER AT A pH NEAR 7.0 IN THE SPRAY-TANK MIX

SPOD-X LC may be applied up to and including the day of harvest and storage.

Limited Warranty: Crop Genetics International, makes no warranty, express or implied including the warranties of merchantability and/or fitness for any particular purpose, concerning this material except those which are contained on this label and/or accompanying technical bulletin.

## SPOD-X LC DRAFT LABELLING Page 5 of 6

## TECHNICAL BULLETIN SPOD-X LC BIOLOGICAL INSECTICIDE

#### PRODUCT DESCRIPTION

SPOD-X LC, produced in the laboratories of Crop Genetics International is an IVP (Insecticidal Virus Product) used to control caterpillars of labelled insect pests.

SPOD-X LC provides a unique opportunity for biological control of insect caterpillars without harmful effects on humans, domestic animals, wildlife, beneficial insects and plants.

SPOD-X LC is a liquid concentrate. Its active ingredient is the nuclear polyhedrosis virus of <a href="Spodoptera">Spodoptera</a> exigua.

Active Ingredient\*

Polyhedral occlusion bodies (OBs) of the nuclear polyhedrosis virus of Spodoptera exigua

0.64%

Inert Ingredients:

99.36

#### **BIOLOGICAL PROPERTIES**

SPOD-X LC belongs to the family Baculoviridae, subgroup A. Numerous virus particles or virions are randomly occluded within a protein paracrystalline matrix called a polyhedral occlusion body (OB). The virions occluded within the OBs are the infectious units. Virions consist of rod-shaped nucleocapsids that are surrounded by an envelope.

The product is rapidly inactivated by temperatures above 90° F. For prolonged storage, the product should be kept below 40° F.

#### MODE OF ACTION

The virus must be ingested to be infective. When infected, at early stages of larval development, infection ultimately results in death. The OBs dissolve within seconds in the midgut after ingestion. The released infectious virions enter the nuclei of the epithelial cells lining the midgut and replicate. Virus progeny enter the hemocoel and infect virtually all cell types, including hemocytes, tracheal cells, fat body cells and epidermal cells. All the cells of tissues are susceptible.

<sup>\*</sup>This lot contains at least 2 billion OBs per ml.

## SPOD-X LC DRAFT LABELLING Page 6 of 6

Assembly of virions and formation of OBs occur only within the nucleus. Lysis of cell and disintegration of larval tissue begin shortly thereafter.

Within a day after ingestion, the usually clear hemolymph becomes increasingly cloudy. Another 1-2 days later, polyhedra-shaped bodies are detected in the blood. Depending on the dose and ambient temperatures, maximum effect on young larvae will occur at 5-7 days after initial ingestion. Shortly after death, larvae become flaccid and the integument ruptures, releasing billions of OBs.

APPLICATION SHOULD BE MADE WHEN LARVAE ARE IN THE FIRST AND SECOND INSTAR. LARVAE MUST INGEST OBS TO BE INFECTED, WHICH IS THE CASE WHEN THEY CONSUME SPRAYED PLANT MATERIAL.

Baculoviruses have been found only in invertebrates; no member of this family is known to infect vertebrates or plants. SPOD-X LC does not reproduce in mammalian cells. No adverse effect to fish, wildlife or beneficial organisms has been observed.

The information contained herein is based on data which are believed to be reliable, but it is understood that such information is not guaranteed by Crop Genetics International Corporation and is to be used at the risk of the user of such information.

Crop Genetics International 10150 Old Columbia Road Columbia, MD 21046 Pages 109-114 - \*Confidential Statements of Formula may be entitled to confidential treatment\*